

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMACEUTICALS INC. and)	
SANOFI-AVENTIS US LLC,)	
)	
Plaintiffs,)	
)	C.A. No. 06-286 (GMS)
v.)	
)	
BARR LABORATORIES, INC.)	
)	
Defendant.)	
)	

**DEFENDANT BARR LABORATORIES, INC.'S
ANSWERING CLAIM CONSTRUCTION BRIEF**

Dated: October 1, 2007

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SUMMARY OF THE ARGUMENT

1. Plaintiffs' brief is littered with bald, unsupported assertions. Noticeably absent, however, is a proper claim construction analysis examining the claim language in the context of the intrinsic record, as required by the Federal Circuit.

2. First, for their construction of "pharmaceutically effective amount," Plaintiffs improperly read out the explicit requirement that the amount of medicament be "effective." Barr's construction, in contrast, properly accounts for this requirement. Because claim terms generally must be interpreted to give effect to all of the words, Barr's construction, not Plaintiffs', is the correct one.

3. Second, Plaintiffs' approach to the construction of "thixotropic" is exactly the opposite of what the Federal Circuit requires. Plaintiffs rely on cherry-picked extrinsic evidence, assessed without reference to the patent specification or prosecution histories, and misapply canons of claim construction in an effort to undermine the applicant's statements of scope in the intrinsic record.

4. Finally, Plaintiffs' constructions of "relatively high" and "relatively low" and the terms' attendant claim clauses improperly read preferred embodiments into the claim terms. At the same time, and again, Plaintiffs improperly disregard the applicant's statements in the intrinsic record setting forth required characteristics of the claimed invention.

5. Plaintiffs' constructions simply do not comport with any accepted Federal Circuit doctrine on claim construction. Barr's, on the other hand, fully comply with controlling Federal Circuit precedent. As such, they are correct and this Court should adopt them.

ARGUMENT

I. The Parties Have Reached Agreement On The Constructions Of “Aqueous Pharmaceutical Composition” And “Mucosal Surfaces.”

The parties have reached an agreement that “aqueous pharmaceutical composition” should be construed as “a water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation.”

The parties have also reached an agreement that “mucosal surfaces” should be construed as “the mucous membranes.”

II. Plaintiffs’ Construction Of “Pharmaceutically Effective Amount” Ignores The Requirement That The Amount Of TAA Be “Effective.”

Plaintiffs’ definition of “pharmaceutically effective amount” cannot be correct for the simple reason that Plaintiffs read the word “effective” out of the phrase. Plaintiffs’ definition would only require the amount of medicament to “exert . . . pharmacological action” and would not require the amount to be “effective.” This is wrong: “claims are interpreted with an eye toward giving effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006); *accord Pause Tech., LLC v. TiVo, Inc.*, 419 F.3d 1326, 1334 (Fed. Cir. 2005) (“Pause attaches no significance to the word ‘predetermine.’ In construing claims, however, we must give each claim term the respect that it is due.”). Plaintiffs’ construction fails to do so in ignoring the word “effective.”

Barr’s construction, in contrast, gives effect to the full scope of the phrase “pharmaceutically effective amount” and is entirely in line with the intrinsic evidence. Barr’s construction is based on the ordinary meaning of the term “effective,” as “having an effect; . . . producing a definite or desired result.” (A353.) Thus, Barr’s construction requires the amount

of TAA to produce the intended pharmaceutical result of relieving the nasal symptoms caused by an abnormal bodily condition such as allergic rhinitis. (A5 at col. 3:59-67.)

Plaintiffs erroneously contend that Barr interprets the term “pharmaceutically effective amount” different in different claims because sometimes Barr refers to the cause of the nasal symptoms as an abnormal bodily condition, as in ‘573 patent claim 1, and other times refers to the cause of the nasal symptoms as allergic rhinitis, as in ‘573 patent claim 21. (Pls.’ Br. at 20.) This is a red herring.¹ Plaintiffs ignore the obvious reason for the superficial difference between the two sets of claims: some of the claims, like ‘573 patent claim 21, expressly require the TAA to treat “allergic rhinitis” while others, like ‘573 patent claim 1, only require the TAA to treat an “abnormal bodily condition.” Thus, Barr’s construction merely specifies the “abnormal bodily condition” as allergic rhinitis in those claims that expressly claim allergic rhinitis. There is nothing improper in this construction.

Plaintiffs also argue that Barr’s construction would render portions of the claims meaningless by misleadingly quoting only parts of the claims and ignoring the relevant remainder. (*See id.* at 21.) Substituting Barr’s construction of “pharmaceutically effective” into claim 1 of the ‘573 patent, as Plaintiffs advocate, actually makes that section of the claim read as follows:

[An amount of triamcinolone acetonide that exerts pharmacological action and provides relief of nasal symptoms caused by the abnormal bodily condition] which is effective in treating an abnormal bodily condition *by virtue of its being present on the mucosal surfaces of the nasal cavity*

¹ There is no substantive difference intended in Barr’s construction between claim 21 of the ‘573 patent and claim 14 of the ‘329 patent. (Pls.’ Br. at 20.) To the extent a substantive difference is suggested, this was merely an oversight. Barr’s construction should read “relief of nasal symptoms caused by allergic rhinitis.”

(A9 at col. 12:61-65 (emphasis added).) Once the remainder of that portion of the claim is added (*i.e.*, “by virtue of its being present . . .”), the claims with Barr’s construction make perfect sense. The amount of TAA must provide the relief of the nasal symptoms *and* must be effective *because* it is in contact with the mucosal surface of the nasal cavity. Thus, properly read in its entirety, that portion of the claim is not rendered meaningless by Barr’s construction.

Finally, as discussed, Barr is not importing limitations into the claims by giving full effect to the phrase “pharmaceutically effective amount.” Rather, Plaintiffs are ignoring the requirement that the amount of TAA be “effective.” A drug that only “exerts pharmacological action” may or may not be “effective.” Plaintiffs’ vague reference to “thousands of patents” as support for its definition is not persuasive. (Pls.’ Br. at 22.) Indeed, the two patents Plaintiffs specifically cite support Barr’s construction. They, too, require the amount of drug to actually do something to treat the disease. (*Id.* at 22-23, *citing* A427 at col. 9:58-61 (an amount “having a *therapeutically relevant effect*”) (emphasis added); A434 at col. 2:32-34 (an “amount sufficient to *ameliorate, prevent or cure said eye disorder*”) (emphasis added).)

Barr’s construction, which “give[s] each claim term the respect that it is due,” is the correct one. *Pause Tech.*, 419 F.3d at 1334; *see also Bicon*, 441 F.3d at 950.

III. The Patents Are Limited To The “Thixotropic” Properties Set Forth In The Specification.

Barr’s approach to the construction of the claim term “thixotropic” is faithful to the Federal Circuit’s teachings in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) because it properly accounts for the representations in the specification and prosecution histories. Plaintiffs’ construction completely ignores the specification and prosecution histories, in direct contravention to *Phillips*. It cannot be correct.

A. Plaintiffs' Construction Ignores The Specification And Prosecution History While Elevating Extrinsic Evidence To Primary Importance.

As is evident from their opening brief, Plaintiffs' approach to construction of the claim term "thixotropic" is completely backwards. Rather than examining the claim term in the context of the patent specification and prosecution histories and only relying on extrinsic evidence to the extent it comports with the intrinsic record, Plaintiffs begin their construction with extrinsic evidence, considered in a vacuum, then consider claim structure, primarily to attack Barr's construction, and almost completely ignore the specification and prosecution histories. (Pls.' Br. at 23-27.) They do not even mention the specification or the prosecution histories until the end of their section on "thixotropic." (*See id.* at 27.) And then, they devote barely a paragraph to the specification and prosecution histories, dismissing them in conclusory fashion without explanation or support. (*Id.*) Apart from citations to specific patent claims, they do not cite to the patents *at all* in their discussion of "thixotropic." In stark contrast, Barr's construction adheres to Federal Circuit precedent by properly grounding that construction in the intrinsic record: the specification – "the single best guide to the meaning of a disputed term" – and the prosecution histories. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

1. Plaintiffs' Unsupported Assertions And Extrinsic Evidence Do Not Reliably Establish The Ordinary Meaning Of "Thixotropic."

As an initial matter, Plaintiffs fail to reliably establish the ordinary meaning of the term "thixotropic" in their construction. Instead, Plaintiffs repeatedly make unsupported assertions and rely on cherry-picked extrinsic evidence. Neither tactic suffices to establish the ordinary meaning of "thixotropic" in the context of the specification.

First, Plaintiffs assert, without citation, that "[t]hixotropy is a rheological effect well-known to those of skill in the art (even if how to cause it is not), and recognized – if not known

by name – by the general public.” (Pls.’ Br. at 23.) Plaintiffs do not offer the Court any evidentiary support for that proposition; rather, they provide a footnote in which they take the Court on an irrelevant detour into ketchup. (*Id.* at 23 & n.3.) Plaintiffs next contend, again as nothing but unsupported assertion, that “thixotropic” is a “term of art” and that, “therefore, consulting extrinsic evidence, such as dictionaries and learned treatises, would be proper in interpreting how one skilled in the art would understand the term.” (*Id.* at 23.) Plaintiffs also baldly submit that the Barnes treatise that they strategically selected to meet their needs is a “seminal treatise in rheology.” (*Id.* at 24.) Yet, again, they offer no support for this assertion.

In reality, Plaintiffs’ definition based on Barnes is not, as Plaintiffs aver, the sole and generally-accepted definition of thixotropy. Numerous dictionaries provide a very different definition that includes no reference to a “gradual time-dependent” recovery.² (*See, e.g.*, A492 (“thixotropy” defined as “the property of certain gels and emulsions of becoming fluid when agitated and then settling again when left at rest”); A496 (“thixotropy” defined as “[t]he property exhibited by certain gels of becoming fluid when stirred or shaken and returning to the semisolid state upon standing”); A499 (same).)

In a footnote, Plaintiffs contend that “other treatises confirm the Barnes’ definition.” (Pls.’ Br. at 24 n.4.) Those “other treatises” cited by Plaintiffs comprise two patents and two documents that appear to be product brochures. None of those references address the context of nasal sprays. And the two patents offer no support for construing “thixotropic” to have a “gradual time-dependent” recovery. For example, U.S. Patent No. 3,035,984 provides that “[t]he products of this invention are obtained initially in the form of thixotropic gels, which, after

² Barr maintains that resort to extrinsic evidence is not proper in the analysis of “thixotropic” because the intrinsic evidence conclusively establishes its definition. But in light of Plaintiffs’ misstatements as to the meaning of the term divorced from the specification, Barr must clarify the state of the extrinsic evidence.

shaking or stirring, flow as liquids but set as gels upon standing.” (A456 at col. 3:4-6.) Similarly, U.S. Patent No. 5,300,302 (the “‘302 patent”) provides that “[t]hixotropy is understood to be the property which the gel has of becoming less viscous when subjected to constant shearing . . . and returning to its initial structure after removal of the shear force and standing for a sufficient time.” (A459 at col. 4:54-59.) Neither of these patents mentions a “gradual time-dependent” return of viscosity.

Moreover, even if these additional references did support the Barnes definition, the fact remains that other, equally valid references support a different definition of “thixotropic.” As the Federal Circuit recently stated,

there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation, each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff.

Phillips, 415 F.3d at 1318. Here, Plaintiffs do just that: cherry-pick extrinsic sources that they think most comport with their desired construction and ignore those extrinsic sources that undermine that construction. Their extrinsic evidence fails to even reliably establish the ordinary meaning of the term.

2. Plaintiffs’ Contrary Extrinsic Evidence Does Not Trump The Intrinsic Record.

Not only is extrinsic evidence susceptible to the type of strategic selection Plaintiffs have employed here, but it also can improperly alter the applicant’s publicly-avowed explanation of his claim terms: “[U]ndue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the ‘indisputable public records consisting of the claims, the specification and the prosecution history,’ thereby undermining the public notice function of patents.” *Id.* at 1319 (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d

1570, 1578 (Fed. Cir. 1995)). Accordingly, extrinsic evidence “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.”

Id. Moreover, focusing on the extrinsic evidence over the intrinsic evidence and

[a]ssigning such a limited role to the specification . . . is inconsistent with our rulings that the specification is “the single best guide to the meaning of a disputed term,” and that the specification “acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the “ordinary meaning” of a claim term is its meaning to the ordinary artisan *after reading the entire patent*. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification. The patent system is based on the proposition that claims cover only the invented subject matter.

Id. at 1320-21 (emphasis added, citations omitted). The Federal Circuit has accordingly condemned “the adoption of a dictionary definition entirely divorced from the context of the written description.” *Id.* at 1321. Yet Plaintiffs urge this very method of claim construction to derive their proposed definition of “thixotropic.”

As Barr established in its opening brief, the patent specification and prosecution histories conclusively establish the proper construction of “thixotropic”. (Barr Br. at 8-18.) What is glaringly absent from Plaintiffs’ analysis and justification for its construction is a discussion of and citation to the specification and prosecution histories. Plaintiffs do not cite to a single part of the specification that supports their alleged ordinary meaning for “thixotropic” for the simple reason that there is none. Indeed, the specification never discusses or even suggests “gradual time-dependent” recovery of viscosity. And, as detailed in Barr’s opening brief, a “gradual” increase in viscosity upon deposit on the mucosal surfaces is inconsistent with the applicant’s recitation of the invention. (Barr Br. at 18.) The invention purportedly allows the composition to remain in place once sprayed and to resist clearance from the mucosal surfaces by mucociliary

forces that are “extremely effective in removing particles from the nose in a rapid manner.” (A4 at col. 1:54-57.) But a composition exhibiting Plaintiffs’ proposed “gradual time-dependent” increase in viscosity could not effectively resist those “rapid” forces.

The Federal Circuit both before and after *Phillips* has warned against “plac[ing] too much emphasis on the ordinary meaning” of a claim “without adequate grounding of that term within the context of the specification.” *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1378 (Fed. Cir. 2006); *see also Southwall*, 54 F.3d at 1577-78 (rejecting testimony on “ordinary meaning” because “neither [expert] testified as to how one skilled in the art would interpret the term ‘sputter-deposited’ when viewed in light of the claims, specification and prosecution history”). And the Federal Circuit has repeatedly emphasized the primacy of the specification: “the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification,” and “the specification is always highly relevant,” “[u]sually, it is dispositive,” and it is “the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1313, 1315 (quoting *Vitronics*, 90 F.3d at 1582).

Plaintiffs also ignore the prosecution history, which supports Barr’s construction and undermines Plaintiffs’. (See Barr Br. at 13-17; A118-A119.) Again, this is contrary to controlling Federal Circuit precedent. *See Hockerson-Halberstadt, Inc. v. Avia Group, Int’l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000) (“[The patentee’s] argument therefore reduces to a request for a mulligan that would erase from the prosecution history the inventor’s disavowal of a particular aspect of a claim term’s meaning. . . . Were we to accept [the patentee’s] position, we would undercut the public’s reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies.”).

Extrinsic evidence should be disregarded where it is “clearly at odds with the claim construction mandated by the claims themselves . . . [and] the written record of the patent.” *Phillips*, 415 F.3d at 1318, 1320-24 (quotation omitted). Thus, while courts may resort to extrinsic evidence, such evidence cannot contradict or overcome the construction compelled by the intrinsic evidence. *Id.* at 1319. Plaintiffs’ extrinsic evidence, divorced from the context of the specification, does not reliably establish the meaning of “thixotropic” in the ‘573 and ‘329 patents. It violates Federal Circuit precedent and the notice function of patents to define “thixotropic” based on extrinsic evidence in a manner incompatible with the specification and prosecution history, as Plaintiffs seek to do here. *See Nystrom v. Trex Co.*, 424 F.3d 1136, 1144-45 (Fed. Cir. 2005) (explaining that patentee “is not entitled to a claim construction divorced from the context of the written description and prosecution history”). Because the applicant consistently and clearly stated that the invention was limited to the specific thixotropic properties detailed in the specification and claims, the term should be construed accordingly.

3. The Claim Structure Does Not Establish The Proper Construction Of “Thixotropic.”

Finally, Plaintiffs suggest that the claim structure confirms its construction of “thixotropic.” (Pls.’ Br. at 24-25.) According to the Plaintiffs, because some claims set forth more specific viscosity parameters than others, there can be no limitations on the “thixotropic” properties of the claimed invention. (*Id.* at 25.)

But the claim structure does not indicate the proper meaning of the term “thixotropic.” The fact that the patentee used additional language to further specify viscosity limits, sometimes using numeric viscosity ranges, does not mean that “‘thixotropic’ does not indicate any specific viscosity limits,” as Plaintiffs contend. (*Id.* at 25.) And it certainly does not mean that the court

should ignore the limitations that the specification and prosecution history place on the claim term “thixotropic.”

Plaintiffs’ reliance on *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005), for its claim context argument is misplaced. In *Datamize*, the Federal Circuit examined the claim context at the patentee’s request, in addressing whether a claim limitation was indefinite. *Id.* at 1349. The court concluded that the claim context *did not* “provide any meaningful definition” for the disputed term. *Id.* Moreover, the court did not elevate the structure of the claims to such importance that it would override the clear limitations in the specification, as Plaintiffs seek to do here. Rather, the court examined the specification for guidance as to the meaning of the claim terms. *Id.* at 1351. The same must be done in this case. *See Phillips*, 415 F.3d at 1313 (“[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.”). And as Barr demonstrated in its opening brief, the specification and prosecution histories conclusively establish the meaning of “thixotropic.” (Barr Br. at 8-18.)

B. Plaintiffs’ Various Superficial Attacks On Barr’s Construction Are Meritless.

Plaintiffs misapply various claim construction canons with limited analysis to attack Barr’s proposed construction of “thixotropic.” In truth, none of Plaintiffs’ criticisms can eliminate the repeated and clear statements in the specification and prosecution histories that the invention was limited to the specific thixotropic properties detailed in the specification and claims.

1. Barr's Construction Does Not Improperly Render Claim Language Surplusage.

Plaintiffs repeatedly argue that Barr's construction improperly renders claim language "surplusage." (*E.g.*, Pls.' Br. at 25.) This argument is without merit.

As an initial matter, "no canon of claim construction is absolute in its application." *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). This includes the canon that claims should be read to avoid surplusage. Surplusage may exist in some claims as a function of the manner in which the claims are written or how they are to be interpreted in view of the specification. *Pickholtz v. Rainbow Tech., Inc.*, 284 F.3d 1365, 1373 (Fed. Cir. 2002) ("Although we would typically be inclined to give meaning to the word 'system,' rather than regard it as surplusage . . . the patent in this case provides no indication that the two terms ['computer' and 'computer system'] mean different things.").

Moreover, the canon of surplusage cannot erase the express representations in the specification and the prosecution history as to the scope of the invention. The patentee does not escape those representations simply because they render some claim language duplicative. The cases relied on by Plaintiffs differ markedly from this case in that, in those cases, the intrinsic evidence dictated the construction that was also supported by the surplusage argument. *See Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed. Cir. 1996) (rejecting a construction not simply because it rendered a claim language superfluous, but because it "was inconsistent with the specification and drawings"; "This is not just the preferred embodiment of the invention; it is the *only* one described. Nothing in the claim language, specification, or drawings suggests that any of the dedicated side or end wall openings may be eliminated, or that an opening may be "adjacent" to more than one wall The patent does not contemplate the openings performing double duty in this manner."); *Texas Instruments, Inc. v. U.S. Int'l Trade*

Comm'n, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (stating that “the specification, prosecution history, and the testimony of the inventors and experts all support” the adopted construction, while the rejected construction rendered claim language surplusage); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1563 (Fed. Cir. 1991) (its construction “gives full effect to the recitation of two distinct elements in the claimed structure: linear border pieces and right angle corner border pieces. It *also* gives full effect to the *specification* and the expert testimony, and a *reasonable interpretation of the prosecution history*.”) (emphasis added). Those cases do not stand for the proposition Plaintiffs advance here that the canon of surplusage overrides the construction dictated by the specification and prosecution histories.

The fact is, surplusage *must* exist in the construction of claims 1 and 5 of the ‘573 patent and claims 1 and 6 of the ‘329 patent; those claims are written in a way that inevitably creates surplusage by using the word “thixotropic” and then describing thixotropic properties. Plaintiffs’ complaint – that Barr’s construction of ‘573 patent claims 1 and 5 and ‘329 patent claims 1 and 6 “renders the term [‘thixotropic’] meaningless, in that it could be removed from the claim and there would be no change in the claim scope” (Pls.’ Br. at 25) – could just as easily be leveled at Plaintiffs’ construction.

Plaintiffs contend that “thixotropic” refers “to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed.” (Pls.’ Br. at 23.) This construction adds nothing to Plaintiffs’ construction of those claims that explicitly recite (i) a relatively high setting viscosity or viscosity of about 400 to 800 or 1000 centipoise, then (ii) a decrease to a relatively low shear viscosity or viscosity of about 50 to 200 centipoise followed by (iii) an increase to the relatively high setting viscosity or viscosity of about 400 to 800 or 1000

centipoise once deposited in the nasal cavity. (*See, e.g.*, D.I. 114, Joint Claim Chart, ‘573 patent at 2-3, 5-6, ‘329 patent at 2-3, 4-5.) According to Plaintiffs, the particular clauses (i)-(iii) require a decrease in viscosity from shear force and then a time-dependent increase of viscosity “upon cessation of shear force and in relatively unstressed form” after being deposited in the nasal cavity. Thus, Plaintiffs construction of “thixotropic” adds nothing that is not already captured in Plaintiffs’ construction of clauses (i)-(iii). Removing their construction of “thixotropic” from those claims would result in no change to the claim scope. While a construction that does not render any language superfluous might, in some circumstances, be preferred over one that does, here, surplusage is unavoidable no matter whose construction is at issue.

2. Barr’s Construction Does Not Apply Different Meanings To “Thixotropic” In Different Claims.

Plaintiffs also incorrectly contend that Barr defines “thixotropic” to mean different things in different claims. (Pls.’ Br. at 25-26.) To the contrary, under Barr’s construction, the term “thixotropic” is consistently interpreted as described in the patent specification. (*See* Barr Br. at 9.) While certain claims contain *additional terms* that further limit or describe the thixotropic properties that must be exhibited by the composition, the meaning of the term “thixotropic” does not change. Rather, it is the other clauses and terms within the claim that further limit the scope of the claim.³

³ Plaintiffs complain that Barr’s construction of claim 34 of the ‘573 patent contains “one substantive difference from their construction of Claims 13 and 25 of the ‘329 patent.” (Pls.’ Br. at 26 n.5.) For ‘329 patent claims 13 and 25, Barr’s construction requires that the “extended period of time [of retention of the composition on the mucosal surfaces] must be greater than 30 minutes.” (D.I. 114, Joint Claim Chart, ‘329 patent at 8, 13.) For ‘573 patent claim 34, Barr did not include the 30-minute retention time within the construction “thixotropic” simply because that claim explicitly specifies in a later clause that the retention time must be “for at least about an hour.” (*Id.*, ‘573 patent at 13.) Thus, the difference stems not from a changing definition of thixotropic, but because of an additional limitation imposed through separate language in ‘573 patent claim 34. Plaintiffs also complain that Barr’s construction of “thixotropic” in ‘329 patent claim 14 is unclear. (Pls.’ Br. at 26 n.6.) Barr’s construction of “thixotropic” is the same in ‘329

Plaintiffs acknowledge that “[t]hose claims that identify ‘following thixotropic properties’ describe rheological properties that vary from claim to claim.” (Pls.’ Br. at 24.) Exactly. While some claims accord the composition the thixotropic properties detailed in the specification, other claims, such as claims 5 and 35 of the ‘573 patent and claims 1 and 26 of the ‘329 patent, further limit the “thixotropic” composition to the explicit numerical ranges for viscosity. It is not the term “thixotropic” that imposes the specific numerical viscosity limitations, but the separate claim terms explicitly setting forth those ranges that do so. Barr’s construction of “thixotropic” – as set forth in the specification – remains the same. Indeed, Barr’s proposed construction of “thixotropic” from claim to claim is just as consistent as Plaintiffs’ construction.

3. The Doctrine Of Claim Differentiation Cannot Overcome The Construction Mandated By The Specification And Prosecution History.

Plaintiffs assert, without support or argument, that Barr’s proposed construction violates the doctrine of claim differentiation. (Pls.’ Br. at 23.) This assertion is fundamentally misplaced. The Federal Circuit has repeatedly rejected patentees’ attempts to use the doctrine as a means of avoiding the impact of express representations in the specification and prosecution history. Moreover, Plaintiffs have not established and cannot establish that the doctrine even applies here.

The Federal Circuit has explained that the doctrine of claim differentiation “is a guide, not a rigid rule.” *Laitram Corp. v. Morehouse, Inc.*, 143 F.3d 1456, 1461 (Fed. Cir. 1998). Claim differentiation “creates only a presumption . . . that can not broaden claims beyond their correct scope.” *Fantasy Sports Props., Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1115 (Fed.

patent claim 14 as in ‘573 patent claim 34 and ‘329 patent claims 13 and 25. The definition is simply placed in clause (B) of claim 14 for ease of review of the claim construction.

Cir. 2002). That presumption is “overcome by a contrary construction dictated by the written description or prosecution history.” *Seachange Int’l v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005).

Indeed, the Federal Circuit has repeatedly cautioned district courts not to accord undue significance to claim differentiation, emphasizing that the doctrine “does not override clear statements of scope in the specification and the prosecution history.” *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999) (construing “restriction ring” to be “part of the cover” even though a dependent claim stated that the ring was “carried to the cover”). The doctrine simply “cannot alter a definition that is otherwise clear from the claim language, description, and prosecution history.” *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997) (declining to use claim differentiation to broaden the scope of the term “passage” to include non-cylindrical structures because the written description consistently described all of the “passage” structures as conical); *Nystrom*, 424 F.3d at 1143 (“Different terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms and phrases is proper.”). Thus, even if the doctrine of claim differentiation applied in this case, it can not override the meaning of “thixotropic” as established by the specification and the applicant’s express representations during prosecution.

Second, the doctrine of claim differentiation does not, in fact, apply here. Claim differentiation is a presumption that claims in the same patent differ in scope. The presumption only applies where a proposed claim construction would render one claim identical in scope to another claim, and therefore would render one claim superfluous. *Curtiss-Wright*, 438 F.3d at 1383. The presumption that claims differ in scope “does not mean that every limitation must be

distinguished from its counterpart in another claim, but only that *at least one* limitation must differ.” *Tate Access Floors, Inc. v. Maxcess Tech., Inc.*, 222 F.3d 958, 968 (Fed. Cir. 2000) (emphasis added, quotations and citation omitted). Thus, the key under claim differentiation analysis is not whether the same words and phrases are found in each claim but whether the claims are of identical scope, thus rendering one of the claims superfluous.

Plaintiffs assert that the “effect of Barr’s proposed construction would be to make all of the claims mean the same thing.” (Pls.’ Br. at 23.) This is wrong. Tellingly, Plaintiffs do not identify a single superfluous claim under Barr’s proposed construction because there is no such claim. For example, claim 34 of the ‘573 patent differs from claim 1 of the ‘573 patent in that, *inter alia*, it is a *method* claim that specifies that “amounts are retained on each of said mucosal surfaces for at least about an hour” whereas ‘573 patent claim 1 is a composition claim. (A9-A10 at cols. 12:59-13:12; A11 at col. 16:5-21.) In another example, claim 13 of the ‘329 patent differs from claim 6 of the ‘329 patent in that, *inter alia*, claim 13 requires that the composition be propellant-free, have a pH of about 4.5 to 7.5, and the composition have the particular ingredients listed. (A21 at cols. 13:37-63, 14:15-29.) There is no reason to go through every pairing of claims within each patent; there simply is no duplicative pair in either patent under Barr’s construction.

Accordingly, the doctrine of claim differentiation cannot be used to alter the clear meaning of “thixotropic” set forth in the specification, or to contradict the prosecution histories. Plaintiffs have, once again, failed to overcome the explicit statements in the specification and prosecution history that establish the meaning of the term. Barr’s construction of the limitation “thixotropic” should be adopted as the correct one.

4. Barr's Construction Does Not Limit The Claims To A Preferred Embodiment.

The only time Plaintiffs actually mention the patent specification, they do not conduct any analysis of it whatsoever. Instead, they state in conclusory fashion that Barr is reading a "single preferred embodiment's characteristics into the claims." (Pls.' Br. at 27.) This does not withstand scrutiny.

The specification does not set forth a "preferred embodiment" in its discussion of the thixotropic nature of the claimed composition. To the contrary, the specification refers to "the" composition of "the present invention" and "the" thixotropic properties it exhibits, repeatedly signaling that there is only one composition claimed and that it has specific thixotropic properties. (See Barr Br. at 12-13.) Those thixotropic properties form the crux of the alleged invention. There is absolutely no indication that any other composition is claimed or that the composition may exhibit any other thixotropic properties. See, e.g., *Honeywell Int'l Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1320 (Fed. Cir. 2006) (holding that, when the patent expressly describes the "present invention," the scope of the claim cannot be broadened beyond this description); *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1348 (Fed. Cir. 2004) ("In light of . . . clear statements in the specification that the invention ('the present system') is directed to communications 'over a standard telephone line,' we cannot read the claims . . . to encompass data transmission over a packet-switched network."). The public "is entitled to take the patentee at his word" that this particular composition with these particular thixotropic properties is his invention. *Honeywell*, 452 F.3d at 1318.

Moreover, as evidenced in the specification, the applicant knew how to specify a characteristic as an embodiment when he so desired by invoking the language of embodiment. The Summary of The Invention clearly illustrates the applicant's choice of language and how it

dictates what is a critical and necessary component of the alleged invention and what is merely an embodiment. The first paragraph introduces that “[i]n accordance with the present invention,” there is a composition with the listed thixotropic properties. (A4 at col. 2:19-39.) The second paragraph then details preferred embodiments of that thixotropic composition: “In preferred form, Also in preferred form” (*Id.* at col. 2:40-46.) The third paragraph returns to the present invention, detailing the corresponding method of using the composition: “Another aspect of the present invention comprises a method for applying” (*Id.* at col. 2:47-63.) Again, the paragraph that follows details preferred embodiments for the method, again introduced by the phrase “[i]n preferred form.” (*Id.* at col. 2:64-65.) The same format appears in the next two paragraphs with respect to the method of preparing the composition, with the characteristics of the alleged invention followed by embodiments. (A4-A5 at cols. 2:66-3:14.)

Throughout the remainder of the specification, the applicant repeatedly invokes language for preferred embodiments flagging them as such, *e.g.*, “preferred,” “preferably,” “for guideline purposes,” “by way of example,” “for example.” (*See, e.g.*, A5-A7 at cols. 4:18-19, 24-27, 61-62; 5:14-18, 32-35; 6:18-25, 27-29, 40-42; 7:32-33.) But never with respect to the description of the thixotropic properties of the composition. Instead, the thixotropic properties of the composition comprise “the composition of the present invention.” (A5 at col. 4:28-59.)

The two portions of the prosecution histories cited by Plaintiffs in their brief likewise do not even suggest that the described thixotropic properties are merely a preferred embodiment. (*See* A98-A100; A191.) In fact, they establish just the opposite. Like the Summary of The Invention section of the specification, the prosecution histories describes the composition with its thixotropic properties as “[a]pplicant’s invention” and “[a]pplicant’s claimed composition,” but then go on to describe other properties as embodiments, *e.g.*, “a preferred medicament,” “[i]n

preferred form, applicant's composition includes a dispersing agent . . .,” and “in preferred form, the composition . . . contains a mixture of stabilizing agents.” (*See* A98-A100.) In fact, the prosecution histories never describe the thixotropic properties set forth in the specification as a preferred form. To the contrary, the prosecution histories clearly indicate that those properties are required. (*See* Barr Br. at 13-17 (citing and quoting A100, A101-A102, A108, A210-A211, A215); *see also* A118-A119.)

The distorted manner in which Plaintiffs approach claim construction is illustrated perfectly in their suggested treatment of preferred embodiments. They seek to confine “relatively low” and “relatively high” viscosities to particular numerical ranges, when those ranges are clearly set forth as embodiments using the language of “for example”, “[b]y way of example”, and “recommended.” (*See* Barr Br. at 21-23; *infra* at pp. 21-24.) At the same time, they ignore the express definition of “thixotropic” set forth in the specification and argue that the declaration of the thixotropic properties as part of “the composition of the present invention” is simply an embodiment, notwithstanding all evidence to the contrary.

IV. Plaintiffs’ Construction Of ‘573 Patent Claim 1 And ‘329 Patent Claim 6 Is Incorrect.

Plaintiffs do not correctly interpret any of the three clauses of ‘573 patent claim 1 and ‘329 patent claim 6. In arriving at their constructions, they improperly read preferred embodiments into the claims and, again, ignore the intrinsic record.

A. Plaintiffs’ Construction Of Clause (i) Of ‘573 Patent Claim 1 And ‘329 Patent Claim 6 Improperly Reads A Preferred Embodiment Into The Claims And Ignores The Claim Term “Gel.”

Plaintiffs improperly construe clause (i) of ‘573 patent claim 1 and ‘329 patent claim 6 as confining the “relatively high” viscosity to its preferred embodiment while reading “gel” out of the claims. These errors confirm that Barr’s construction of the clause – consistent with the

ordinary meaning informed by the specification and prosecution histories – is the only proper meaning.

1. Plaintiffs Improperly Try To Limit “Relatively High” To A Particular Embodiment When The Prosecution Histories Clearly Establish That The Term Should Be Accorded Its Ordinary Meaning.

While Barr construes the term “relatively high” in accordance with its ordinary meaning as informed by the prosecution histories,⁴ Plaintiffs incorrectly argue that the specification defines “relatively high” as being “400 to about 1000 cps.” In fact, the specification does not contain a definition of “relatively high” and instead makes it clear that the numerical range is only a preferred embodiment. The Federal Circuit has repeatedly cautioned against limiting a claim term expressed in general descriptive words to a numerical range. Contrary to Federal Circuit precedent, Plaintiffs misread the specification to improperly convert an embodiment into a limitation while completely ignoring the very explicit definition of the term contained in the prosecution histories.

To support their restriction of the term “relatively high” to a specific embodiment, Plaintiffs quote one sentence of the specification: “The viscosity of the composition at rest is relatively high, *for example*, about 400 to about 1000 cp.” (Pls.’ Br. at 28; A5 at col. 4:39-41 (emphasis added).) That sentence does not define “relatively high”; rather, it is just a preferred embodiment. The use of the term “for example” makes that abundantly clear. *See, e.g., Websidestory, Inc. v. Netratings, Inc.*, No. 06-CV-408, 2007 WL 2019654, at *6 (S.D. Cal. July

⁴ Barr misstated in its opening brief that “the term ‘relatively’ appears in the specification only when preceding the term ‘high’ or ‘low.’” (Barr Br. at 21.) In fact, the term “relatively” only appears in the *claims* when preceding the term “high” or “low,” but does appear in the specification before other terms, such as “relatively long periods of time.” It remains true, though, that the specification does not expressly or implicitly define “relatively” different from its ordinary meaning. And it also remains true that the specification never defines “relatively high” or “relatively low.”

10, 2007) (rejecting party's attempts to improperly "read limitations from a specification into a claim," specifically noting that "the limitations proffered by Netratings appear in dependent claims, and the limitations are often preceded with language such as 'for example,' 'exemplary,' or 'in the preferred embodiment'"). A second passage of the specification further confirms that the numerical range is an embodiment: "[b]y way of example, a setting viscosity of about 400 to about 800 cp is *recommended* for a composition containing an anti-inflammatory steroid, for example, triamcinolone acetonide." (A6 at col. 5:14-17 (emphasis added).) Using the language "[b]y way of example," "for example," and "recommended," the patents could not be clearer that the numerical range for the setting viscosity is an embodiment. Moreover, when the applicant wanted to limit the viscosity to a numerical range, he did exactly that by explicitly setting forth that range in the claims. (*See, e.g.*, A10 at col. 13:20-46; A21 at col. 13:2-25.) This further compels the conclusion that the range is merely a preferred embodiment. *Renishaw*, 158 F.3d at 1249 ("[W]hen a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims."); *Conoco, Inc. v. Energy & Envt'l Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006) (refusing to limit the claim term "water-alcohol mixture" to a numerical range found in the specification where the specification stated that the "amount of alcohol employed in the suspending material may vary widely but it usually forms between about 0 and 70 weight percent of the suspending material and more usually between about 30 and about 50 weight percent").

In addition to distorting the meaning of the specification, Plaintiffs ignore that part of the prosecution histories where the applicant actually put the public on notice as to the definition of "relatively." The applicant very clearly stated during prosecution that, "[w]ith respect to the Examiner's comments on the term 'relatively', this term is used *in its normal way* to compare

qualitatively the composition in its ‘high’ viscosity form with the composition in its ‘low’ viscosity form.” (A108 (emphasis added)). Accordingly, the applicant made it clear that the term “relatively high” simply means that the viscosity is higher than when it is in its lower, i.e., shear, viscosity. This portion of the prosecution histories, ignored by Plaintiffs, is entirely consistent with, and in fact mandates, the ordinary meaning of the term.

Plaintiffs also make much of the fact that Barr does not include a methodology for measuring viscosity within its construction, allegedly because “measured viscosity may depend on the method (and equipment) for measurement.” (Pls.’ Br. at 28-29.) But that only holds true under Plaintiffs’ incorrect construction of the term as being limited to a numerical range. The use of any particular type of equipment is not necessary to determine if the viscosity decreases under shear, and will not tell you if the viscosity is “sufficiently high to hold and maintain the particle of TAA suspended and dispersed substantially uniformly in the composition.”

2. Plaintiffs Inexplicably Dispute That The Setting Composition Must Be A Gel Even Though The Claims Explicitly Require It.

In a perplexing paragraph, Plaintiffs take issue with Barr’s inclusion of the term “gel” in its construction of this clause. (Pls.’ Br. at 29-30.) Plaintiffs appear to be arguing that the term “gel” and “having [TAA] particles suspended therein” are the same claim limitation and therefore Barr erred in separating those two requirements. (*Id.*) This is nonsense. The claim term says both “gel” and “having said particles suspended *therein* [*i.e.*, in the gel].” (A10 at col. 13:3-4 (emphasis added).) Under Barr’s construction, the composition must both be a gel and have the particles suspended therein, just as the claims expressly require.

In any event, while Plaintiffs’ complaint about Barr’s inclusion of “gel” in its construction is not at all clear, the issue before the Court is simple. There is no dispute among the parties that the claims require the TAA particles to be suspended and dispersed substantially

uniformly in the composition. Moreover, there does not appear to be a dispute among the parties over the ordinary meaning of the word “gel.” The intrinsic evidence does not define the term, and Barr would generally construe “gel” as “[a] colloid in which the disperse phase combines with the dispersion medium to produce a semisolid material.” (A495.)⁵ This does not appear to be substantively different than Plaintiffs’ bald assertion that “a basic definition of a ‘gel’ is a colloidal system (that is, a type of suspension) with certain properties of a solid.” (Pls.’ Br. at 29.)

The only dispute is whether the claims require the composition at rest to be a gel. They do: “the viscosity of the composition in unsheared form is relatively high, with the composition being a *gel* having said particles suspended therein.” (A10 at col. 13:1-4; *see also* A21 at col. 13:46-49 (same).) Plaintiffs’ construction completely ignores this claim term and, accordingly, cannot stand under Federal Circuit precedent. *Bicon*, 441 F.3d at 950; *Pause Tech.*, 419 F.3d at 1334.

B. Plaintiffs’ Construction Of Clause (ii) Of ‘573 Patent Claim 1 And ‘329 Patent Claim 6 Likewise Improperly Reads A Preferred Embodiment Into The Claims.

For clause (ii) of the ‘573 patent claim 1 and ‘329 patent claim 6, Plaintiffs are again improperly importing an embodiment into a claim limitation while ignoring the ordinary meaning and the intrinsic evidence. Once again, Plaintiffs attempt to redefine the term in litigation far differently than the definition advanced by the applicant during the prosecution of the patents.

⁵ Barr did not provide a construction for the word “gel” in its claim construction because it did not believe such a construction was necessary. If the Court deems such a construction necessary, Barr would propose the construction discussed in the text above.

As an initial matter, Plaintiffs assert that “Barr’s definition fails to define ‘relatively low’ at all.” (Pls.’ Br. at 31.) To the contrary, both the Joint Claim Chart and Barr’s opening brief set forth Barr’s construction of a “relatively low” viscosity as a viscosity “lower than the setting viscosity.” (*See, e.g.*, D.I. 114, Joint Claim Chart, ‘573 patent at 3; Barr Br. at 24.)

Moreover, for the same reasons that Plaintiffs’ limited construction of “relatively high” is incorrect, Plaintiffs’ construction of “relatively low” is incorrect. Ignoring the ordinary meaning of the term as informed by the specification, Plaintiffs construe “relatively low” as “rang[ing] from about 50 to about 200 cps when measured by the method disclosed in the specification.” (D.I. 114, Joint Claim Chart, ‘573 patent at 3.) There is no sentence in the specification containing both the term “relatively low” and the proposed numerical range of about 50 to about 200 centipoise. The only two sentences in the specification that do recite that numerical range use clear language to label it as a preferred embodiment. One sentence calls the range a “*recommended* shear viscosity” while the other introduces the range by the phrase “*for example.*” (A6 at col. 5:17-18; A5 at col. 4:43-45 (emphasis added).) This numerical range is simply an embodiment. *See, e.g., Websidestory*, 2007 WL 2019654, at *6. Furthermore, like “relatively high,” “relatively low” is a generally descriptive term, which the Federal Circuit has stated should not ordinarily be limited to a numerical range, particularly since the range is explicitly set forth in certain claims such as ‘573 patent claim 5 and ‘329 patent claim 1. *Renishaw*, 158 F.3d at 1249.

Finally, and again, during prosecution the applicant confirmed that “relatively” should be interpreted according to its ordinary meaning: “[w]ith respect to the Examiner’s comments on the term ‘relatively’, this term is used *in its normal way* to compare qualitatively the composition in its ‘high’ viscosity form with the composition in its ‘low’ viscosity form.” (A108 (emphasis

added).) Plaintiffs violate Federal Circuit precedent by ignoring and contradicting such explicit statements in the prosecution history. *See Southwall*, 54 F.3d at 1576 (“Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.”).

C. Plaintiffs’ Construction Of Clause (iii) Of ‘573 Patent Claim 1 And ‘329 Patent Claim 6 Is Nonsensical And Fails To Comport With The Intrinsic Record.

Plaintiffs’ construction of clause (iii) of ‘573 patent claim 1 and ‘329 patent claim 6 must be rejected because it requires construction itself and fails to provide an understandable test for infringement. In addition, it is inconsistent with the specification and prosecution history. By contrast, Barr’s construction is faithful to the intrinsic evidence and provides an objective and measurable means of determining infringement.

1. Plaintiffs’ Construction Is Incomplete And Inconsistent With Both Plaintiffs’ Prior Construction Of “Relatively High” And Their Dispute With Barr’s Construction.

Plaintiffs offer a confusing and improper construction for clause (iii) of ‘573 patent claim 1 and ‘329 patent claim 6. Plaintiffs’ construction provides, *inter alia*, that the “the viscosity of the composition increases to *a relatively high value such that* the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucocillary forces, and *reverts to the viscosity in unsheared form.*” (Pls.’ Br. at 32 (emphasis added).) But Plaintiffs fail to properly define a “relatively high value” of a viscosity and give no understandable meaning to their “reverts to the viscosity in unsheared form” construction.

In Plaintiffs’ construction, they fail to identify what they think is a “relatively high value” of a viscosity. Plaintiffs appear to be defining the term differently than in clause (i) and collapsing into one the two viscosity requirements in the claim: *i.e.*, that it be “relatively high” and “such that it resists being cleared from the mucosal surfaces.” Conflating two separate

requirements is exactly what Plaintiffs erroneously claim Barr did with respect to the shear viscosity, as discussed above. (*See supra* at p. 25.) Barr did not do so for that clause, and Plaintiffs cannot properly do so for this clause.

Moreover, and rather bizarrely, although Plaintiffs concede that the viscosity “reverts to the viscosity in unsheared form,” they do not appear to limit “relatively high” to the numerical range they advance for the “relatively high” unsheared viscosity in clause (i). Plaintiffs offer no explanation or justification for this inconsistency, nor is there any such justification. *See Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1345 (Fed. Cir. 1998) (“[T]he same word appearing in the same claim should be interpreted consistently.”).

In addition, it is impossible to understand what Plaintiffs mean by their proffered construction that the deposited composition “reverts to the viscosity in unsheared form.” Plaintiffs quarrel with Barr’s construction that the composition must return to its setting viscosity. But, it is undisputed that the viscosity in unsheared form is the setting viscosity. So how does the deposited composition “revert to the viscosity unsheared form” but not “return to its setting viscosity?” That simply cannot be. Plaintiffs offer no explanation for these contrary positions nor does their claim construction approach comport with any accepted Federal Circuit doctrine. Plaintiffs’ construction of “relatively high” in clause (iii), to the extent is comprehensible, cannot be correct.

2. The Setting Viscosity Applies Both To The Unsheared Form And The Deposited Form: In Deposited Form the Composition Must Return To A Gel And Its Setting Viscosity.

Plaintiffs take issue with Barr’s assertion that, in deposited form, the composition “returns to a gel and to its setting viscosity.” (Pls.’ Br. at 32-33.) Plaintiffs contend that “*nothing* in the intrinsic evidence” requires the composition to return to the viscosity in unsheared form because “the terms ‘gel’ and ‘setting viscosity’ are used only in relation to the

unsheared form, not the deposited form” of the composition. (Pls.’ Br. at 32-33 (emphasis added).) This is patently untrue.

First, the claim terms use exactly the same claim term, “relatively high,” in clause (i) to describe the viscosity of the composition at rest and in clause (iii) to describe the composition in deposited form. This alone demonstrates that the viscosity in deposited form must be the same as before shear is applied. *See Digital Biometrics*, 149 F.3d at 1345 (“[T]he same word appearing in the same claim should be interpreted consistently.”). But there is more.

Contrary to Plaintiffs’ assertions, the specification explicitly defines the “setting viscosity” as the composition’s viscosity both prior to the application of shear and upon deposit on the mucosal surfaces of the nasal cavity:

For convenience, the viscosity of the composition at rest is referred to as the “setting viscosity” and the viscosity of the composition which is shaken is referred to as the “shear viscosity.” The *setting viscosity* of the composition should be sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition *and* to retain for an extended period of time the composition *on the mucosal surfaces on which it is deposited* in the nasal cavities, that is, the composition resists being swept away by the mucocillary forces which are present in the nasal cavities. The shear viscosity of the composition is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist.

(A5-A6 at cols. 4:63-5:9 (emphasis added).) Thus, according to the specification, the “setting viscosity” is the same both before shear is applied (“sufficiently high to hold and maintain the particles dispersed substantially uniformly in the composition”) and in deposited form in the nasal cavity (“and to retain for extended period of time the composition on the mucosal surfaces on which it is deposited”). Moreover, as set forth in Barr’s opening brief, this portion of the specification makes clear that the specification defines only two, not three, viscosities: (1) a “setting viscosity” both when the composition is at rest and when it deposits on the mucosal surfaces of the nasal cavity; and (2) a “shear viscosity” when the composition is subjected to

shear or shaken. There is no third separate viscosity discussed anywhere in the patent. (*See* Barr Br. at 26-27.) Plaintiffs simply disregard this portion of the specification.⁶

In addition, the specification clearly establishes that, in deposited form, the composition must return to the same gel as it is before shear is applied. The specification states:

The thixotropic nature of the composition at rest (not subject to shear) can be described as *a gel* in which the particles of medicament are dispersed and suspended substantially uniformly In deposited and relatively unstressed form, the composition increases in viscosity and *assumes its gel-like form* which includes particles of the medicament suspended in the composition and which resists being cleared from the nasal passages by the inherent mucocillary forces that are present in the nasal cavities.

(A5 at col. 4:36-62 (emphasis added).) The composition is a “gel” at rest and “*assumes its gel-like form*” when deposited on the mucosal surfaces of the nasal cavity.

Plaintiffs acknowledge this passage in a footnote but attempt to downplay its significance. (Pls.’ Br. at 33 n.7.) They argue that “gel” is used to describe only the initial unsheared composition while the “specification uses a different term – gel-like – at places to describe the deposited form” and that “[t]he use of a different term would suggest that it has a different meaning.” (*Id.*) The terms “gel” and “gel-like form” are equivalent, however. The specification uses them interchangeably to refer to the setting viscosity; for instance, compare “(i) the viscosity of the [com]position in unsheared form is relatively high, with the composition being in *gel-like form*” (A4 at col. 2:29-30), with “[t]he thixotropic nature of the composition at rest (not subject to shear) can be described as a *gel*” (A5 at col. 4:36-38 (emphasis added)). A few sentences later the specification notes that in deposited form the composition “assumes its

⁶ Even the ‘302 patent, which Plaintiffs rely on for their definition of “thixotropic” (Pls.’ Br. at 24 n.4), explicitly supports this requirement: “Thixotropy is understood to be the property which the gel has of becoming less viscous when subjected to constant shearing . . . and *returning to its initial structure* after removal of the shear force and standing for a sufficient time.” (A459 at col. 4:54-59 (emphasis added).)

gel-like form” (A5 at col. 4:54-55), clearly referring back to the composition being a “gel” prior to the application of shear. Accordingly, this supports Barr’s construction that, when deposited, the composition returns to the same gel-like form, *i.e.*, the gel, that it was in before application of shear. *See Pickholtz*, 284 F.3d at 1372-73 (holding that two terms have the same meaning where nothing in the patent explicates their relationship or indicates any difference in meaning).

The equivalency of gel and gel-like form is also confirmed by the prosecution history. Again, the applicant described the composition at rest as being in “gel-like form.” (A98.) Application claim 8 recited “(i) the viscosity of the position in unsheared form is relatively high, with the composition being *in gel-like form*.” (A66 (emphasis added).) In response to the Examiner’s rejection on grounds of indefiniteness under 35 U.S.C. § 112 (*see* A82), the applicant amended that claim to recite “(i) the viscosity of the position in unsheared form is relatively high, with the composition being in a gel-like form having said particles suspended therein.” (A94 (emphasis in original).) The applicant then stated, “Claim 8 has been amended to define *the gel-like form* of the composition as having suspended therein the solid particles of medicament. The Examiner’s attention is directed to the present application, pages 9 and 10, wherein there is a detailed discussion of the composition and the thixotropic nature thereof, *including the nature of the freely flowable liquid form of the composition and its gel-like form*.” (A108 (citing A45-A47) (emphasis added).) In other words, the applicant told the Patent Office that there are two forms – freely flowing liquid and gel-like – not three. Furthermore, the applicant made clear that the composition before shear is applied is “gel-like.” The Patent Office simply did not like the use of the term “gel-like,” indicating a preference of the term “gel.” (A112 (“[T]he metes and bounds of ‘gel-like’ are not defined. Amending the claim to ‘gel’ would obviate this rejection.”).) Subsequently, the applicant used the term “gel” in the claim,

rather than “gel-like” and thereafter obtained allowance. (A187.) Clearly the applicant deemed the two terms equivalent.

3. Plaintiffs’ Opposition To The Requisite Immediate Return To Setting Viscosity Is Unfounded.

Plaintiffs’ dispute with Barr’s construction requirement that the deposited composition *immediately* return to the setting viscosity underscores another instance where Plaintiffs’ construction ignores the specification’s assertions as to the purported invention. And Plaintiffs commit the very errors in claim construction analysis of which they accuse Barr.

Plaintiffs accuse Barr of “tak[ing] remarkable liberties in construing this claim term, using language that does not appear anywhere in the patent,” pointing out that “the word ‘immediate’ does not appear in the patents-in-suit.” (Pls.’ Br. at 33.) Yet, neither do the patents contain the words “gradual” or “time-dependent.” And they certainly do not use those words to describe the composition’s increase in viscosity once deposited on the mucosal surfaces.

Moreover, Plaintiffs’ construction, unlike Barr’s, lacks any support in the intrinsic record. The specification contains no discussion of any allotment of time for the viscosity to increase following deposit on the mucosal surfaces, nor is any such allotment of time even suggested. And Plaintiffs ignore both the claim language and specification in disputing the “immediate” return to viscosity. The language of the claims and the specification require that the composition exhibit the setting viscosity upon deposit on the mucosal surfaces of the nasal cavity, without any allotment of time for the viscosity to increase following deposit. The claims clearly state that the composition “is” in its setting viscosity “in deposited form” – not “following deposit” or “some time after deposit.” (A10 at col. 13:9-10; A21 at col. 13:54-56.)

Furthermore, the claims require the viscosity in deposited form be “such that it resists being cleared from the mucosal surfaces by the inherent mucociliary forces which are present in

the nasal cavity,” and the composition must have already reached its setting viscosity to effectively resist those “rapid” forces. As previously explained, a “gradual” increase in viscosity would mean that the composition will have already been swept away by the “extremely effective” and “rapid” mucocillary forces to another region of the body where the medicament cannot perform its topical function by the time the composition has returned to its setting viscosity. (A4 at col. 1:50-55.)

While Plaintiffs repeatedly accuse Barr of ignoring the claims’ context and structure to advance Plaintiffs’ constructions, Plaintiffs fail to recognize the import of the claims’ use of the word “is” to describe the viscosity both prior to the application of shear and in deposited form in contrast to the use of “becomes” to describe the shear viscosity. The applicant’s use of the term “becomes” for when the composition is shaken plainly suggests some time for the viscosity to lower. In stark contrast, the applicant’s deliberate use of the term “is” and not “becomes” for when the composition is relatively high in deposited form affords no time for the viscosity to increase following deposit on the mucosal surfaces. (*See* Barr Br. at 29-30.) The viscosity must already be relatively high once it is deposited. Plaintiffs’ construction is thus clearly in error.

4. Retention Of The Composition On The Mucosal Surfaces For An Extended Period Of Time Is Not A Preferred Embodiment.

Barr proposes a definition for the deposited viscosity that is based on the specification and actually allows one to assess whether an accused product infringes. More specifically, Barr’s construction offers an objective test for how long the composition must remain on the mucosal surfaces of the nasal cavity. Plaintiffs’ construction, on the other hand, does not.

Plaintiffs contend that “the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucocillary forces, and reverts to the viscosity in unsheared form.” (D.I. 114, Joint Claim Chart, ‘573 patent at 3; ‘329 patent at 5.) Yet,

significantly, they fail to say how long it must be retained. Two seconds? Clearly not, or it would not perform any function according to the theory of the invention. How about five hours? One week? Plaintiffs' construction itself requires construction and leaves the test for infringement unanswered.

In contrast, Barr properly relies on the specification for its proposed construction for the retention of the deposited composition. The specification requires the setting viscosity to be:

sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition and *to retain for an extended period of time the composition on the mucosal surfaces on which it is deposited* in the nasal cavities, *that is, the composition resists being swept away by the mucociliary forces* which are present in the nasal cavities.

(A5-A6 at cols. 4:66-5:6 (emphasis added).) The specification thus clearly equates resistance from being swept away by mucociliary forces with remaining on the mucosal surfaces for "an extended period of time." The specification also explains:

the medicament should remain in contact with the target tissues for relatively long periods of time. The longer the medicament remains in contact with the target tissues, the greater the opportunity for the medicament to perform its function. In order to remain in contact with the target tissues, the medicament must be capable of resisting those forces in the nasal passages that function to remove particles from the nose. Such forces, referred to as 'mucociliary clearance,' are recognized as being extremely effective in removing particles from the nose in a rapid manner, for example, within 10-30 minutes from the time the particles enter the nose.

(A4 at col. 1:45-57.) That portion of the specification makes it clear the viscosity must be sufficient to resist mucociliary forces for at least 30 minutes.

This is not a preferred embodiment, as Plaintiffs aver. Plaintiffs primarily rely on their argument that the explicit definition of setting viscosity is somehow a preferred embodiment that applies only to the composition before the application of shear. (Pls.' Br. at 33.) But Barr has already explained why this is both incorrect and illogical. (*See supra* at pp. 27-31.) Barr's

construction is not an embodiment but rather a necessary and integral part of “the composition of the present invention.”

In fact, the preferred embodiments set forth in the patent are directed to retention for longer than an hour. The specification provides that, “[i]n accordance with the present invention, the medicament remains in contact with the target tissues for relatively long periods of time, *for example*, at least about an hour and for even two or more hours.” (A5 at col. 3:22-26 (emphasis added).) That preferred embodiment is also set forth in a dependent claim. For example, claim 34 of the ‘573 patent recites that the deposited composition “resists being cleared from the mucosal surfaces for at least about an hour.” (A11 at col. 16:19-20.) “At least about an hour” is a subset of “greater than 30 minutes.” Barr’s construction, which provides an actual test for infringement, is the only proper construction pursuant to the intrinsic evidence.

5. Plaintiffs’ Definition Of The Term “Mucocillary Forces” Is No Clearer Than The Claim Term Itself.

Finally, Plaintiffs contend that its construction of “mucocillary forces” as “those that cause mucocillary clearance” must be adopted because Barr erred in not specifically defining that claim term. (Pls.’ Br. at 34; D.I. 114, Joint Claim Chart, ‘573 patent at 3; ‘329 patent at 5.) First, Plaintiffs’ definition is no more illuminating than the term itself, and is not altogether consistent with the specification. The specification equates “mucocillary clearance” with “mucocillary forces,” and does not indicate that “mucocillary forces” *cause* “mucocillary clearance” as Plaintiffs contend. (A4 at col. 1:53.)

Either way, Barr need not define that specific term, since Barr’s construction explains that “the composition resists being swept away by the mucociliary forces present in the nasal cavity” equates to the setting viscosity being “sufficiently high to retain for an extended period of time the composition on the mucosal surfaces on the nasal cavity.” (D.I. 114, Joint Claim

Chart, '573 patent at 3.) No further definition of mucociliary forces is necessary. But if the Court deems one is required, then the more precise definition of the term is found in the specification: "those forces in the nasal passages that function to remove particles from the nose." (A4 at col. 1:50-53.)

CONCLUSION

For these reasons and those set forth in Barr's opening brief, Plaintiffs' proposed claim constructions should be denied and the Court should adopt Barr's construction of the relevant claim terms.

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CERTIFICATE OF SERVICE

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